



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

EIZO CORPORATION  
c/o HIROAKI HASHIMOTO  
153 SHIMOKASHIWANO  
HAKUSAN, ISHIKAWA 924-8566  
JAPAN

November 21, 2014

Re: K143261

Trade/Device Name: 2.3MP Color LCD Monitor, RadiForce MX242W

Regulation Number: 21 CFR 892.2050

Regulation Name: Picture archiving and communications system

Regulatory Class: II

Product Code: PGY

Dated: November 11, 2014

Received: November 13, 2014

Dear Mr. Hashimoto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert A. Ochs".

for

Janine M. Morris  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K143261

Device Name

2.3MP Color LCD Monitor, RadiForce MX242W

Indications for Use (Describe)

This product is intended to be used in displaying and viewing digital images for review and analysis by trained medical practitioners. It does not support the display of mammography images for diagnosis.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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EIZO Corporation, 153 Shimokashiwano, Hakusan, Ishikawa  
924-8566 Japan

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Name	Hiroaki Hashimoto
Department	Medical System Standards
Telephone	+81 (76) 274-2468
Fax	+81 (76) 274-2484
E-Mail	hiroaki.hashimoto@eizo.com

## 510(k) Summary (in accordance with 21 CFR 807.92)

### 1. Company

EIZO Corporation  
153 Shimokashiwano, Hakusan  
Ishikawa 924-8566 Japan  
Tel: +81 (76) 274-2468  
Fax: +81 (76) 274-2484

### 2. Contact Person

Hiroaki Hashimoto

### 3. Date of Summary

November 20th, 2014

### 4. Device Information

- Trade Name/Model: RadiForce MX242W
- Common Name: 2.3MP Color LCD Monitor
- Classification Name: Display, Diagnostic Radiology
- Regulation Number: 21 CFR 892.2050, Product Code PGY

### 5. Predicate Device

- 3.7MP Color LCD Monitor, RadiForce MX270W (K113240)

## **6. Device Description**

RadiForce MX242W is a color LCD monitor for viewing medical images other than those of mammography. The color panel employs in-plane switching (IPS) technology allowing wide viewing angles with the matrix size (or resolution) of 1,920 x 1,200 pixels (2.3MP).

Since factory calibrated display modes, each of which is characterized by a specific tone curve (including DICOM GSDF), a specific luminance range and a specific color temperature, are stored in lookup tables within the monitor, the tone curve is e.g. DICOM compliant regardless of the display controller used.

RadiCS is application software to be installed in each workstation offering worry-free quality control of the diagnostic monitors including the RadiForce MX242W based on the QC standards and guidelines and is capable of quantitative tests and visual tests defined by them. The RadiCS and its subset, RadiCS LE, are included in this 510(k) submission as an accessory to the RadiForce MX242W.

## **7. Intended Use**

This product is intended to be used in displaying and viewing digital images for review and analysis by trained medical practitioners. It does not support the display of mammography images for diagnosis.

## **8. Comparison of Technological Characteristics**

The comparison table below enumerates information derived from the product brochure of the each device and different technological characteristics are discussed in it:

Attributes	RadiForce MX242W	RadiForce MX270W	Explanation of Differences
<b>Display Performance/Specifications</b>			
Screen technology	IPS TFT Color LCD Panel	IPS TFT Color LCD Panel	-
Viewing angle (H, V)	H: 178°, V: 178°	H: 178°, V: 178°	Eizo uses typical data for very low contrast provided by the panel manufacturers
Resolution	2.3MP (1,920 x 1,200)	3.7MP (2,560 x 1,440)	The panel used by the proposed device is smaller and provides lower resolution (= smaller matrix size).
Aspect ratio	16 : 10	16 : 9	
Active screen size	518.4 mm x 324.0 mm	596.7 mm x 335.6 mm	
Pixel pitch	0.270 mm x 0.270 mm	0.233 mm x 0.233 mm	If one cares about the different pixel size, the perceived pixel size similar to that of the predicate device can be realized easily by adjusting the viewing distance.
Maximum luminance	350 cd/m <sup>2</sup>	300 cd/m <sup>2</sup>	-
DICOM calibrated luminance	180 cd/m <sup>2</sup>	170 cd/m <sup>2</sup>	-
Contrast ratio	1000 : 1	1000 : 1	Eizo uses typical contrast ratio data provided by panel manufacturers.
Backlighting	LED	LED	-
Display Colors	From a palette of 68 billion colors: - 10-bit input (DisplayPort): 1.07 billion colors (maximum) - 8-bit input: 16.77 million colors	From a palette of 68 billion colors: - 10-bit input (DisplayPort): 1.07 billion colors (maximum) - 8-bit input: 16.77 million colors	-
Luminance non-uniformity compensation	Digital Uniformity Equalizer	Digital Uniformity Equalizer	-
<b>Video Signal Input</b>			
Input video signals	DVI-I x 1, DisplayPort x 1	DVI-D x 1, DisplayPort x 1	The proposed device supports an analog video

Scanning Frequency (H, V)	Digital: 31 - 76 kHz / 59 - 61 Hz (VGA Text: 69 - 71 Hz) Frame synchronous mode: 59 - 61 Hz Analog: 26 - 76 kHz / 49 - 71 Hz (VGA Text: 69 - 71 Hz) Frame synchronous mode: 59 - 61 Hz	31 - 89 kHz, 29.5 - 61 Hz (VGA Text: 69 - 71 Hz) Frame synchronous mode: 29.5 - 30.5 Hz, 59 - 61 Hz	interface, which has been supported by other devices cleared for 510(k) like RadiForce RS210 (K092613).
<b>Power Related Specifications</b>			
Power Requirements	AC 100 - 240 V, 50 / 60 Hz	AC 100 - 120 V, 200 - 240 V: 50 / 60 Hz	-
Power Consumption / Save Mode	68 W / Less than 0.5 W	93 W / Less than 1 W	The proposed device consumes less power.
Power Management	Digital: DVI DMPM, DisplayPort 1.1a Analog: VESA DPM	DVI DMPM, DisplayPort 1.1a	VESA DPM, a power management feature for analog video interface, is supported by the proposed device.
<b>Miscellaneous Features/Specifications</b>			
QC software	RadiCS	RadiCS	-
Sensors	Backlight Sensor	Backlight Sensor, Integrated Front Sensor	The both devices are capable of QC tests and calibration with an external sensor.
USB Ports / Standard	1 upstream, 2 downstream / Rev. 2.0	1 upstream, 2 downstream / Rev. 2.0	-
Dimensions w/o stand (W x H x D)	575 x 398 x 71 mm	646 x 402 x 72.5 mm	Different housing design due to the different panel size.

It is clear that the technological characteristics differences discussed above do not affect the safety and the effectiveness of the MX242W.

## 9. Performance Testing

The following bench tests were performed on the RadiForce MX242W.

- Verification of the conformance to DICOM GSDF as specified in *Assessment of Display Performance for Medical Imaging Systems* by AAPM Task Group 18 (TG18 guideline)
- Measurement of the luminance non-uniformity characteristics of the display screen as specified in the TG18 guideline
- Measurement of the chromaticity non-uniformity characteristics of the display screen as specified in the TG18 guideline
- Measurement of the chromaticity at the center of the display screen at 5%, 50% and 95% of the maximum luminance as specified in *Guidance for Industry and FDA Staff: Display Accessories for Full-Field Digital Mammography Systems-Premarket Notification (510(k)) Submissions*
- Visual check of presence or absence of miscellaneous artifacts on the display screen as specified in the TG18 guideline
- Measurement of spatial resolution expressed as modulation transfer function (MTF)
- The maximum number allowed for each type of pixel defects/faults

The test results showed that the RadiForce MX242W has display characteristics equivalent to those of the predicate device, RadiForce MX270W, except two items, each of which was determined that it would not affect observer's performance.

Besides, the display characteristics of the RadiForce MX242W meet the pre-defined criteria when criteria are set.

No animal or clinical testing was performed on the RadiForce MX242W.

## 10. Conclusion

The RadiForce MX242W was determined to be substantially equivalent to the predicate device due to the following reasons:

- The stated intended use is substantially the same as that of the predicate device.
- It was confirmed that the technological characteristics different from those of the predicate device do not affect the safety and the effectiveness.
- The bench tests demonstrated that the display characteristics are equivalent to those of the predicate device except two items, each of which was determined that it would not affect observer's performance.